UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

LAURA PURICELLI, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case No. 4:10CV01793 JCH
	)	
GENETECH, INC. and	)	
BIOGEN IDEC, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motion for Judgment on the Pleadings Pursuant to Federal Rule of Civil Procedure 12(c) (Doc. No. 36). These matters are fully briefed and ready for disposition.

STANDARD OF REVIEW

As a general rule, a Rule 12(c) motion for judgment on the pleadings is reviewed under the same standard as a 12(b)(6) motion to dismiss. Ginsburg v. InBev NV/SA, 623 F.3d 1229, 1233, n.3 (8th Cir. 2010); Clemons v. Crawford, 585 F.3d 1119, 1124 (8th Cir. 2009), cert. denied, 130 S. Ct. 3507, 177 L. Ed. 2d 1092 (2010); Ashley County v. Pfizer, 552 F.3d 659, 665 (8th Cir. 2009). That is, the Court must view the allegations in the Complaint liberally in the light most favorable to Plaintiff. Eckert v. Titan Tire Corp., 514 F.3d 801, 806 (8th Cir. 2008) (citing Luney v. SGS Auto Servs., 432 F.3d 866, 867 (8th Cir. 2005)). Additionally, the Court "must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." Coons v. Mineta, 410 F.3d 1036, 1039 (8th Cir. 2005) (citation omitted). A complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v.

Twombly, 550 U.S. 544, 570 (2007) (abrogating the "no set of facts" standard for Fed. R. Civ. P. 12(b)(6) found in Conley v. Gibson, 355 U.S. 41, 45–46 (1957)). A plaintiff's obligation to provide the grounds of his entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555; Huang v. Gateway Hotel Holdings, 520 F. Supp. 2d 1137, 1140 (E.D. Mo. 2007).

When considering a motion for judgment on the pleadings, "the Court generally must ignore materials outside the pleadings, but it may consider 'some materials that are part of the public record or do not contradict the complaint,' Missouri ex rel. Nixon v. Coeur D'Alene Tribe, 164 F.3d 1102, 1107 (8th Cir.), cert. denied, 527 U.S. 1039, 119 S. Ct. 2400, 144 L. Ed. 2d 799 (1999), as well as materials that are 'necessarily embraced by the pleadings.' Piper Jaffray Cos. v. National Union Fire Ins. Co., 967 F. Supp. 1148, 1152 (D. Minn. 1997)." Porous Media Corp. v. Pall Corp., 186 F.3d 1077, 1079 (8th Cir. 1999).

When the Court exercises its power under diversity jurisdiction, it interprets the forum state's law. Gray v. AT&T Corp., 357 F.3d 763, 765 (8th Cir. 2004). Missouri law applies to this diversity case. Triton Corp. v. Hardrives, Inc., 85 F.3d 343, 345 (8th Cir. 1996). The Court attempts to predict how the highest court in Missouri would resolve these issues. Nordyne, Inc. v. Int'l Controls & Measurements Corp., 262 F.3d 843, 846 (8th Cir. 2001).

BACKGROUND

Defendants Genetech and Biogen are pharmaceutical companies that jointly developed, market and sell Rituxan. (Petition ("Pet."), Doc. No. 6, ¶¶12-16).[1] The use of Rituxan has side effects. Patients who receive Rituxan can suffer profound immunosuppression, which can lead to

[1]Plaintiffs also named Defendant Dorothy Guccione, the Senior Oncology Clinical Coordinator at Genetech (Pet., ¶¶9-10), as a defendant but she was dismissed pursuant to this Court's Order (Doc. No. 24).

serious and untreatable illnesses such as community viral infections or progressive multifocal leukoencephalopathy (PML). (Pet., ¶21).

Plaintiffs are the children of the decedent, Mary Merrick ("Merrick" or "the Decedent"). (Pet.,¶¶1-3). Merrick first was administered Rituxan in February 2009. (Pet., ¶18). On October 21, 2009, Merrick died as a result of PML. (Pet., ¶23).

Plaintiffs filed a Petition alleging causes of action for Wrongful Death-Strict Liability (Count I), Wrongful Death-Negligence (Count II), Wrongful Death & Negligent Misrepresentation (Count III), Punitive Damages (Count IV). The Petition was removed to this Court on September 24, 2010. (Doc. No. 1). On March 17, 2011, Defendants Genetech, Inc. and Biogen Idec, Inc. moved for judgment on the pleadings. (Doc. No. 36).

DISCUSSION

I. MOTION FOR JUDGMENT ON THE PLEADINGS

As stated, Plaintiffs allege causes of action for strict liability, negligence, and negligent misrepresentation, arising from the death of Merrick from PML, which Plaintiffs claim result from Merrick's use of Rituxan. Plaintiffs allege that their mother and her physician were not adequately warned about the dangers of Rituxan. (Plaintiff's [sic] Response to Defendants Motion for Judgment on the Pleadings ("Response"), Doc. No. 38, p. 2) ("Defendants placed an unreasonably dangerous product into the stream of commerce and failed to adequately warn the decedent and further misrepresented the dangers of the product to consumers and physicians.").

A. Counts I - III

In Missouri, a products liability case can be based on strict liability, breach of warranty, or negligence. For products liability to be founded in negligence, the plaintiff must prove the existence of a duty, the defendant's breach thereof, and proximately caused damages. Morrison v. Kubota

Tractor Corp., 891 S.W.2d 422, 425 (Mo. Ct. App. 1994)(citing Commercial Distribution Ctr., Inc. v. St. Regis Paper Co., 689 S.W.2d 664, 671 (Mo. App. 1985)).

Defendants assert that they did not breach any duty because "Ms. Merrick's physician received a warning about the risks of PML and death and exercised independent medical judgment as to whether use of the medication was appropriate." (Defendants' Memorandum in Support of Their Motion for Judgment on the Pleadings ("Memorandum"), Doc. No. 37, p. 11). Defendants further state that "the warning at issue in this case is adequate as a matter of law." (Id.).

Defendants assert that the warning provided to Decedent's physician was adequate as a matter of law under the learned intermediary doctrine. (Id., pp. 7-12). The learned intermediary doctrine "assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects." Hill v. Searle Laboratories, Div. of Searle Pharmaceuticals, Inc., 884 F.2d 1064, 1070 (8th Cir. 1989).[2] Defendants state that Merrick's physician received a copy of Rituxan's warning which stated in a bold-text black box: "JC virus infection resulting in PML and death can occur in patients receiving Rituxan." (Memorandum, pp. 1-3; Exhibit 37-2).[3] Likewise, the warning was reprinted

[2]"There are several arguments supporting the application of this exception to prescription drug products. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and drug manufacturer. Second, the information regarding risks is often too technical for a patient to make a reasonable choice. Third, it is virtually impossible in many cases for a manufacturer to directly warn each patient." Hill, 884 F.2d at 1070; see also Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1033 (E.D. Mo. 2007) (citing In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 815 (E.D. Texas 2002)("[c]ourts have identified the following rationales for the doctrine: 1) states want to preserve the doctor-patient relationship which could be undermined if patients received warnings from drug manufacturers that differed from doctor's warnings; 2) physicians are in a better position to convey information to patients than manufacturers; 3) manufacturers lack an efficient means to communicate warnings to individual consumers; and 4) states are concerned that patients cannot comprehend complex medical information, and it is too burdensome for pharmaceutical companies to translate medical jargon into understandable language.").

[3]Defendants assert that the Rituxan label is "necessarily embraced by the pleadings," and does not cause their Motion to be converted into one for summary judgment. Ginsberg v. InBev NV/SA,

in the Physicians' Desk Reference. See Exhibit 37-3, 2010 Physicians' Desk Reference (64th ed.). In addition, the Rituxan label also warned that it should be prescribed only if other medications failed. See Memorandum, pp. 4-5. Finally, Defendants provided a Medication Guide to Rituxan users that warned about the risks of PML. See Memorandum, pp. 5-6. Plaintiffs admit that the Decedent received this Medication Guide. (Memorandum, p. 5; Pet., ¶25)(admitting Decedent received a "warning pamphlet").

In turn, Plaintiffs assert that the Defendants failed to provide the "proper warning" to the Decedent's physician. (Response, p. 2 (citing Madsen v. American Home Prod. Corp., 477 F.Supp.2d 1025 (E.D. Mo. 2007)). Plaintiffs assert that the Court must accept as true their allegation that the warning provided was not proper. (Response, p. 2).[4]

The cases cited by Defendants, save one case from New Jersey, were summary judgment decisions.[5] In their Reply, Defendants primarily rely on Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 382, 384 (App.Div. 2006), for the proposition that this Court can find Rituxan's

649 F. Supp. 3d 943, 946 (E.D. Mo. 2009). (Memorandum, p. 2, n. 2). Plaintiffs reference the label in their Petition. (See ¶¶19-21).

[4]Although it does not decide this issue, Defendants correctly point out that Plaintiffs cannot rely on mere "threadbare recitals" of legal elements and jargon to defeat a motion to dismiss. Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009)(citing Twombly, 550 U.S. at 555)("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under Twombly). The mere allegation that a warning was not "proper," without providing any facts to support that claim, is insufficient.

[5]See Memorandum, pp. 8-9 (citing Ehlis v. Shire Richwood, Inc., 367 F.3d 1013 (8th Cir. 2004) (affirming district court's grant of summary judgment); Meridia Prods. Liab. Litig. v. Abbott Labs., 447 F.3d 861, 384 (6th Cir. 2006) (affirming district court's grant of summary judgment); Ziliak v. Astra Zeneca L.P., 324 F.3d 518, 521 (7th Cir. 2003) (affirming district court's grant of summary judgment); Caveny v. Ciba-Geigy Corp., 818 F. Supp. 1404, 1406 (D. Colo. 1992) (granting defendant's motion for summary judgment); Cather v. Catheter Technology Corp., 753 F. Supp. 634, 636 (S.D. Miss. 1991)(granting defendant's motion for summary judgment); Jacobs v. Dista Products Co., 693 F. Supp. 1029, 1036 (D. Wyo. 1988) (granting defendants' motion for summary judgment)); Memorandum, p. 10 (citing In re Rezulin Prods. Liab. Litig., 331 F. Supp. 2d 196, 203 (S.D.N.Y. 2004) (granting defendants' motion for summary judgment)); see also Memorandum, p. 11 (citing Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 406 (Mo. Ct. App. 1999) (affirming jury verdict for the defendant)).

warnings to be adequate as a matter of law based solely on the pleadings. (See Defendants' Reply to Plaintiffs' Opposition to Defendants' Motion Pursuant to Federal Rule of Civil Procedure 12©, Doc. No. 40, pp. 1, 3).[6] Banner, however, is not controlling authority for this Court. Furthermore, the Court does not have the same facts, as in Banner, that the Decedent and her physician were aware of the warnings and deliberately ignored them. In Banner, as part of the protocol for using Accutane, the patient had to participate in a pregnancy prevention program. Pursuant to that protocol, the patient had to complete a "Patient Information/Consent and Survey Enrollment Form" before she could receive a prescription for Accutane. 383 N.J. Super. at 369-70. Based upon the Accutane package insert, the Patient Information/Consent and Survey Enrollment Form and the other warnings provided to Ms. Banner and her physician, the court determined that the warnings given to Ms. Banner were "accurate, clear, and unambiguous," and were, therefore, adequate as a matter of law. Id. at 382. The court held that "Roche fulfilled its duty by advising of the risks associated with

[6]In Banner, the plaintiffs were warned about the risks of severe birth defects if the wife became pregnant while taking Accutane, a prescription drug for the treatment of acne. 383 N.J. Super. at 368-71. The couple participated in the pregnancy prevention program developed by Roche, and the couple agreed to remain abstinent while the wife was treated with Accutane. Id. at 369-72 The couple did not remain abstinent, and they had an extremely disabled child. Id. at 372. The couple brought an action against Roche under New Jersey's Products Liability Act, N.J.S.A. 2A:58C-1 to -11. The appellate court affirmed the trial court's dismissal of the action and held that "the warnings Roche supplied were adequate as a matter of law, whether the warnings are viewed from the perspective of Ms. Banner herself or her physician who wrote the prescription. Roche satisfied its duty to warn of the dangers attendant to Accutane therapy, whether Roche owed a duty to Ms. Banner or to her physician." Id. at 377. The Banner court engaged in a three step process: (1) an ascertainment of the seriousness of the involved risk, (2) an evaluation of the language "for its accuracy, clarity and relative consistency," and (3) consideration of the warning as a whole, to determine "if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Id. at 379-80. The Banner court concluded that the warnings provided were "direct, unequivocal and forceful," and that the warnings as to the consequences of becoming pregnant with Accutane were "unmistakable." Id. at 380. Thus, the court held that the warnings given to Debbie Banner in 1995 were "accurate, clear, and unambiguous," and were, therefore, adequate as a matter of law. Id. at 382.

Accutane therapy and advising of the need for either effective contraception or abstinence." Id. at 383.

The unique factual situation in Banner, however, is not present here. Here, the Court has neither subjective nor objective information regarding whether the warning provided to the Decedent and her physician was sufficient. Plaintiffs do not allege that the Decedent or her physician filled out a consent form acknowledging the risks associated with Rituxan, including PML. Although Plaintiff admits that the Decedent received a "warning pamphlet" with her prescription (Pet., ¶25), there is no evidence that she or her physician read and understood this warning or that this warning was adequate under the circumstances. Cf. Ziliak, 324 F.3d at 521 ("Here Ziliak does not dispute that Dr. Amodio was aware of AstraZeneca's warnings, and that he took the risks that Ziliak would develop adverse side effects into account when prescribing Pulmicort."); see also Jacobs, 693 F. Supp. at 1034 ("Deposition testimony of plaintiff's current treating physician, Dr. Bush, indicates that the warnings were adequate."). In fact, as the court in Banner acknowledged, "ordinarily, the question of whether a warning is adequate is one for a jury to resolve." Id. at 378; see also In re Rezulin Prods. Liab. Litig., 331 F. Supp. 2d 196, 199 (S.D.N.Y. 2004) ("[T]he adequacy of a warning usually is a question of fact for a jury. In appropriate cases, however, a warning may be held adequate as a matter of law and the issue resolved on summary judgment.").

Thus, the Court cannot determine that the warnings provided to the Decedent's physician were adequate as a matter of law, based solely on the pleadings.[7] The Court requires additional evidence, usually in the form of expert testimony, that the warnings adequately informed the

[7]This is particularly true under a subjective standard because Ms. Merrick's physician allegedly prescribed Rituxan even though she had never received a prior tumor necrosis factor (TNF) antagonist therapy. (Pet., ¶19). According to Plaintiffs, Rituxan should not be used except in adult patients "with moderate to severely active rheumatoid arthritis (RA)" who have inadequately responded to "one or more" prior TNF antagonist therapies. (Pet., ¶17; see also Sullivan Decl., Doc. Nos. 37-1 and 37-1, Ex. B).

Decedent's physician of Rituxan's risks. For example, in Ehlis v. Shire Richwood, Inc., the Court analyzed the evidence under both subjective and objective standards regarding whether the physician was aware of the risk of the medication, Adderall, from the manufacturer's warnings. Id. at 1018-19. With respect to the former, the treating physician testified that he knew of the risks of Adderall, that he believed the warnings were adequate, and that he prescribed it knowing those risks. Id. at 1018. On the objective side, there was expert witness testimony that the warning was appropriate under the FDA standard, which was "also the standard for the pharmaceutical industry." 367 F.3d at 1018. None of this type of evidence is present here, and the Court denies Defendants' Motion for Judgment on the Pleadings because the Court cannot find that warnings were adequate as a matter of law based solely on the pleadings.

B. Punitive Damages

Defendants assert that the punitive damages count should be dismissed for the same reasons as Counts I-III. Specifically, Defendants claim that Plaintiffs' allegations for punitive damages are "threadbare recitals" of legal elements and do not contain the factual allegations required. (Memorandum, p. 12) (citing Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) and Bell Atl.Corp. v. Twombly, 550 U.S. 544 (2007)).

Although it will not dismiss Plaintiffs' punitive damage claim based upon the reasons stated by Defendants, the Court notes that "[a] punitive damage claim is not a separate cause of action and any claim for punitive damages must be brought in conjunction with a claim for actual damages. Robison v. JPMorgan Chase & Co., 4:10CV226, 2010 U.S. Dist. LEXIS 62322, at *10 (E.D. Mo. June 23, 2010)(citing Klein v. Gen Elec. Co., 728 S.W.2d 670, 671 (Mo. Ct. App. 1987)). Accordingly, the Court dismisses Count IV for failure to state a claim. The Court affords Plaintiffs

seven (7) days from the date of this Order to file an amended complaint, including any request for punitive damages as part of the prayer for relief in a claim for actual damages.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion for Judgment on the Pleadings Pursuant to Federal Rule of Civil Procedure 12(c) (Doc. No. 36) is **DENIED**, in part, and **GRANTED**, in part. Plaintiffs are granted seven (7) days to file an amended complaint in accordance with this Order.

Dated this 26th day of April, 2011.

/s / Jean C. Hamilton
UNITED STATES DISTRICT JUDGE